

REMARKS

By this Amendment, claims 24-26 and 33 have been amended. New claims 40-43 have been added to further define the claimed invention. The subject matter recited by claims 40-43 is supported throughout the specification as originally filed, for example, on page 6, lines 19-27. No new matter has been added.

I. Claims 24-39 Fully Comply with the First Paragraph of 35 U.S.C. 112

Claims 24-39 are rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the written description requirement. More specifically, the Examiner contends in paragraph 3 of the Office Action that:

- (a) There is no description, either generic or specific, of any of the methods recited in claims 24-37.
- (b) The written description of the invention as it is described in the specification requires, at a minimum, the use of a chemical moiety of the structure depicted at page 6, line 20 which structure is not required in any of the methods of claims 24-37.
- (c) There is no description in the specification of the sequence of steps recited in any of independent claims 24-26 and 33. The generic description of the invention set forth at page 24 of the specification, Inducing the emission of electromagnetic radiation, does not describe any of the steps or required limitations (for example, in claim 24, “a chemical moiety *which is not oxidized to a high oxidation state at said electrochemical potential*” and “said electrochemical potential *oxidizing said agent but not said chemical moiety*”) recited in the instant claims.

- (d) There is no description in the specification of the generic terms “chemical moiety” and “agent”.

Applicants submit that the function of the written description requirement is to ensure that a patent is granted to inventors who had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by them; how the specification accomplishes this is not material. *In re Smith*, 178 U.S.P.Q. 620 (C.C.P.A. 1973). Therefore, the test for written description under 35 U.S.C. §112, first paragraph, is whether the originally filed specification reasonably conveys to a person having ordinary skill that Applicants had possession of the subject matter later claimed. *In re Kaslow*, 217 U.S.P.Q. 1089 (Fed. Cir. 1983); *see also*, M.P.E.P., § 2163.02.

If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the written description requirement is satisfied. *See, e.g., Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 U.S.P.Q.2d 1111, 1116 (Fed. Cir. 1991); *Martin v. Johnson*, 454 F.2d 746, 751, 172 U.S.P.Q. 391, 395 (C.C.P.A. 1972) (stating “the description need not be in *ipsis verbis* [i.e., “in the same words”] to be sufficient”). The subject matter of the claim need not be described literally (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the written description requirement. M.P.E.P. § 2163.02.

Applicants submit that the claims are fully supported by the specification as originally filed. Prior to the present Amendment, claim 24, for example, recited:

24. A method for detecting the presence of a chemical moiety comprising the steps of:
(a) forming a mixture comprising

- (i) an agent which forms a reductant upon exposure of the mixture to an electrochemical potential sufficient to oxidize said agent, and
- (ii) a chemical moiety which is not oxidized to a high oxidation state at said electrochemical potential and is capable of emitting electrochemiluminescence;
- (b) applying electrochemical potential to the mixture, said electrochemical potential oxidizing said agent but not said chemical moiety;
- (c) inducing the chemical moiety to emit electrochemiluminescence;
- and
- (d) detecting said electrochemiluminescence.

Claim 24 is supported by the specification as originally filed. For example, the specification teaches:

The present invention provides methods for determining the presence of the novel chemical moieties. The present invention also provides methods of determining the presence of a chemical moiety as described above. The methods comprise:

- a) forming a reagent mixture under suitable conditions containing the chemical moiety;
- b) inducing the moiety to emit electromagnetic radiation by exposing the reagent mixture to chemical energy or electrochemical energy; and
- c) detecting the emitted electromagnetic radiation and thereby determining the presence of the chemical moiety.

This invention further provides for the use of lanthanide-containing labels in binding methods for determining the presence of substances of interest. These methods may be used to determine labeled moieties of interest, to employ labeled moieties to determine analytes of interest, or to use labelled analogues of analytes of interest to determine analytes of interest in competitive binding assays. These binding methods may be homogeneous or heterogeneous binding methods.

Still further, the present invention provides systems for determining the presence of the lanthanide-containing chemical moieties of this invention. These systems comprise a means for inducing the chemical moiety to emit electromagnetic radiation.

Specification at 7, lines 4-29.

Moreover, Example 2 describes the use of a mixture comprising an agent which forms a reductant upon exposure of the mixture to an electrochemical potential sufficient to oxidize said agent and a chemical moiety (Eu chelate) which is not oxidized

to a high oxidation state at the electrochemical potential and is capable of emitting electrochemiluminescence:

Example 2: Effect of TPA on Electrochemiluminescence of Eu*

Cyclic voltammograms were established for 2 mM europium chelate in 0.1 M TBAPF₆ acetonitrile solution and for 2 mM europium chelate with 10 mM TPA added in 0.1 M TBAPF₆ acetonitrile solution. Both voltammograms were established with a glassy carbon electrode (diameter=3 mm) at a scan rate of 0.1 Volts/second. The results are depicted, respectively, in FIGS. 1(a) and 1(b). The results confirm that the electrochemiluminescence of Eu* is directly caused by the oxidation of TPA.

Thus, Example 2 describes a method of generating electrochemiluminescence wherein an electrochemical potential is applied which oxidizes the agent (e.g., TPA), but not the label (i.e., Eu chelate). Specifically, the cyclic voltammogram for a europium chelate (Figure 1A) shows only a reduction wave and shows no oxidation occurring even at oxidation potentials as high as about 1.2 V. Figure 1B shows that on addition of TPA there is a strong oxidation wave at approximately 0.9 V due to the oxidation of TPA. The observation of ECL in the presence of TPA shows that ECL can be generated at a potential that allows for oxidation of TPA (the agent) but no oxidation of the chemical moiety (the europium chelate).

Because at least these portions of the as-filed application support the methods and steps recited by claims 24-39, Applicants respectfully request that the rejection set forth in Paragraphs 3(a) and (c) of the Office Action be withdrawn.

With respect to Paragraphs 3(b) and (d) of the Office Action, there is no basis to assert that the "specification requires, at a minimum, the use of a chemical moiety of the structure depicted at page 6, line 20" in order to comply with the written description requirement of the first paragraph of 35 USC 112. The specification discloses

numerous electrochemiluminescent labels in addition to the lanthanide-containing labels described by the formula referenced by the Examiner. For example, the specification teaches that organic compounds, including rubrene and 9,10-diphenyl anthracene are suitable labels. Page 4, lines 25-27. In addition, the specification discloses that many organometallic compounds, including those comprising osmium or ruthenium, are suitable electrochemiluminescent labels. Page 4, lines 27-33. The Examiner has provided no basis for concluding that one skilled in the art would not understand that these non-lanthanide-containing electrochemiluminescent labels were not within the scope of the claimed methods.

Applicants submit that the term “agent” is also used throughout the specification, For example, the specification teaches:

Inducing the Emission of Electromagnetic Radiation

The methods of the present invention may be performed by exposing the reagent mixture to electrochemical energy or to chemical energy. Additionally, the reagent mixture may be exposed to a combination of electromagnetic radiation, chemical energy, and electrochemical energy.

The chemical moiety may be oxidized by exposure to an energy source. Such an energy source may be a chemical oxidizing **agent**. Examples of such oxidizing agents include CE(IV) salts or PbO.sub.2. Furthermore, the chemical moiety may be reduced by exposure to an energy source. Such an energy source may be a chemical reducing **agent**. An example of a suitable reducing agent is magnesium.

Specification at 24, lines 9-22 (emphasis added).

Accordingly, it is unclear why the Examiner contends that the specification does not provide written support for these terms. Applicants respectfully remind the Examiner that the subject matter of a claim need not be described literally (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement (MPEP 2163.02).

For the above reasons, Applicants respectfully request that the rejection set forth in Paragraphs 3(b) and (d) of the Office Action be withdrawn.

II. The Claims are Definite

Claims 24-39 are rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Office Action at 3.

Applicants respectfully submit that the focus during the examination of claims for compliance with 35 U.S.C. § 112, second paragraph, is whether the claims meet the threshold requirements of clarity and precision, not whether more suitable language or modes of expression are available. M.P.E.P. § 2173.02. Terms in the patent claims are not too vague unless they prevent one skilled in the art from understanding, in light of the specification, what is claimed. *Andrew Corp. v. Gabriel Electronics, Inc.*, 6 U.S.P.Q.2d 2010 (Fed. Cir. 1988); *U.S. v. Teletronics, Inc.*, 8 U.S.P.Q. 2d 1217 (Fed. Cir. 1988); *Specialty Composites v. Cabot Corp.*, 6 U.S.P.Q.2d 1601 (Fed. Cir. 1988).

Moreover, the definiteness of claim language must be analyzed, not in a vacuum, but in light of (1) the content of the particular application disclosure, (2) the teachings of the prior art, and (3) the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. M.P.E.P. § 2173.02. Applicants urge the claims fully meet the requirements of 35 U.S.C. § 112, second paragraph.

In the Office Action, the Examiner asserts:

- (a) The following terms render the claims indefinite in the absence of any description of the nature, structure and scope of these terms in the specification: “chemical moiety”, “agent”, and “analyte of interest”.
- (b) The exact scope of the following claim limitations cannot be determined: the extent of oxidation of the “agent” and “a high oxidation state”.

With respect to Paragraph 4(a) of the Office Action, Applicants submit that one of ordinary skill in the art would readily understand the meaning of the terms “chemical moiety”, “agent” and “analyte of interest” when the terms are properly construed in view of the specification and what is known in the prior art. The Examiner has provide no reason to conclude otherwise. If the scope of subject matter embraced by a claim is clear and if the Applicant has not otherwise indicated that she intends the claim to be of a different scope, then the claim particularly points out and distinctly claims the subject matter which the applicant regards as her invention. *In re Borkowski*, 164 U.S.P.Q. 642 (CCPA 1970); *In re Robins*, 166 U.S.P.Q. 552 (CCPA 1970). Breadth alone is not indefiniteness. *In re Gardner*, 166 U.S.P.Q. 138 (CCPA 1970;); *In re Conley*, 180 U.S.P.Q. 454 (CCPA 1974); *Ex parte Lewis*, 197 U.S.P.Q. 543 (Bd. App. 1977). Accordingly, the Examiner’s suggestion that the “description of the nature, structure, and scope of these terms in the specification” is required to be inserted in the claims is without merit.

With respect to Paragraph 4(b) of the Office Action, Applicants submit that one of ordinary skill in the art would understand the meaning of the term “a high oxidation state” and the extent of oxidation of the agent, when the terms are properly construed in view of the specification and what is known in the art. However, to further the

prosecution of the application, Applicants have amended the claims to recite "higher oxidation state" rather than "high oxidation state". Applicants submit that the chemical moiety is not oxidized at the potential that is applied. Therefore, it is believed the amendment to the claims resolves any clarity issues since "higher" is relative to the original oxidation state of the chemical moiety and thus indicates that the oxidation state of the chemical moiety is not increased by the applied potential.

Applicants respectfully request the reconsideration and withdrawal of the rejection under

35 U.S.C § 112, second paragraph.


In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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